IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
	*	
v.	*	**CRIMINAL NO. 10-cr-694-RWT**
	*	
LAUREN STEVENS,	*	
	*	
Defendant	*	
	*	
	*	
	*******	

UNITED STATES' INITIAL RESPONSE TO DEFENDANT'S MOTION FOR JUDGMENT OF ACQUITTAL

I. Introduction

The United States respectfully requests that the Court deny the defendant's Rule 29 motion, or at a minimum reserve ruling until the jury has returned a verdict. In this pleading, the United States will not be able to respond in full in less than 24 hours to the defendant's 31-page motion. The United States requests the opportunity to file a complete response later in the trial.

In short, however, this case should not be taken away from the jury. The United States satisfied in its case in chief the elements for all six charges. Viewed in the light most favorable to the prosecution, the United States has proven that the defendant violated the charged obstruction statutes both by affirmatively providing false and fraudulent information to the Food and Drug Administration ("FDA") and by withholding information she had promised to provide, even while telling the FDA that the company's responses were final and complete. The evidence has also been enough to satisfy a reasonable jury that the defendant knowingly and purposefully made false statements in the February, March, May, and November 2003 letters to the FDA

regarding GlaxoSmithKline's ("GSK") promotion of Wellbutrin, the company's advisory boards, and compensation provided to attendees at promotional speaker programs.

The defendant's lack of good faith has been established by the contrast between what she knew and what she told the FDA, demonstrated most starkly by her own notes and the notes of other participants that reflect the calculated way in which she chose to deceive the FDA and not follow through on her commitments to provide information covered by the FDA's request, while telling the FDA that he responses were final and complete. Although the pro-con memo is powerful evidence that shows the defendant knew the information she was withholding demonstrated "incriminating" evidence of the off-label promotion of Wellbutrin for weight loss and other unapproved uses, it is far from the only evidence that has been introduced showing the defendant's lack of good faith. The defendant's paralegal also testified that the answer the defendant planned to give the FDA – if asked explain her failure to produce the documents – was "untrue." The defendant already had consent from the physicians to provide their materials to the FDA, but she intended to tell the FDA that she still had to seek such consent. There has been no affirmative evidence to support the defendant's requested inference that she reasonably relied in good faith on legal advice to make false statements or engage in obstruction. Whether she relied in good faith on other attorneys involved in the effort – who either tacitly blessed portions of her behavior or did not tell her it was criminal (and the evidence demonstrated they did not have all the information that Ms. Stevens had) – is a question of fact for the jury to decide. Thus, the real issue here is the defendant's intent, a classic jury question.

Further, the evidence of the defendant's guilt is contained not only in the testimony the Court has heard, but also in the voluminous exhibits that have been admitted into evidence. A

Rule 29 order before the jury has returned a verdict is rare; it is even less appropriate in this case, where the Court has instructed the government not to have witnesses testify about or read documents that are in evidence, on the grounds that the prosecution can discuss such information during closing arguments.

In fairness to the United States, the Court should follow its usual practice of holding off on any Rule 29 ruling until the jury has returned a verdict. The evidence presented supports conviction. The United States, the grand jury, the petit jury, and the Court have devoted significant resources to this matter. To deprive the jury of the opportunity to weigh the evidence in this case, where even in the defendant's opening counsel conceded that inaccurate statements were made to the FDA about issues where defendant knew the true facts, would be an extraordinary act by the Court. It is particularly important here, where a lawyer stands accused of crimes, that her conduct be judged by a jury of the people. This is important both to fulfill the purpose of our jury system and to avoid the perception of unfairness that a corporate lawyer need not be judged by a jury of the people. There is no good reason not to reserve ruling on the motion until the jury has returned its verdict.

II. Argument

A. The Evidence Must Be Viewed in the Light Most Favorable to the Government and All Reasonable Inferences Must Be Drawn in the Government's Favor

Federal Rule of Criminal Procedure 29(a) provides that "[a]fter the government closes its evidence or after the close of all the evidence, the court on the defendant's motion must enter a judgment of acquittal of any offense for which the evidence is insufficient to sustain a conviction." A motion for acquittal under Rule 29 should be denied "if there is substantial

evidence, taking the view most favorable to the Government" to support a conviction. *United States v. Steed*, 674 F.2d 284, 286 (4th Cir.), *cert. denied*, 459 U.S. 829 (1982). When making such a determination, the Court must "consider both circumstantial and direct evidence, and allow the government all reasonable inferences that could be drawn in its favor." *United States v. Harvey*, 532 F.3d 326, 333 (4th Cir. 2008).

The Court may not substitute its own judgment for that of the jury. "Instead, the relevant question is whether *any* rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt." *Jackson v. Virginia*, 443 U.S. 307, 319 (1979) (emphasis in original); *see also United States v. Lentz*, 383 F.3d 191, 199 (4th Cir. 2004); *United States v. Reid*, 523 F.3d 310, 317 (4th Cir. 2003) (holding that a conviction must be sustained if, viewing the evidence is the light most favorable to the government, there is "evidence that a reasonable finder of fact could accept as adequate and sufficient to support a conclusion of a defendant's guilt beyond a reasonable doubt"). "Courts must be vigilant not to usurp the role of the jury by weighing credibility and assigning weight to the evidence or by substituting its judgment for that of the jury." *United States v. Flood*, 2008 WL 2278612 (D. Del. 2008) (quoting *United States v. Brodie*, 403 F.3d 123, 133 (3d Cir. 2005)). Under this standard, the defendant's motion should be denied. The United States also refers this Court to a matter that is contemporaneously being filed under seal.

B. The United States Has Provided Substantial Evidence of the Defendant's Guilt With Respect to Count One

1. The Evidence Has Demonstrated that the Defendant Engaged in Obstruction

The defendant contends she did not conceal anything because (1) the defendant never

told "FDA that she had not received any decks from the doctors"; and (2) the FDA's letter was in the form of a voluntary request rather than a subpoena. *See* Def.'s Mot. J. Acquittal (ECF 183) at 5-6. As a result, the defendant argues, she could not have violated § 1512(c)(2).

As an initial matter, the defendant mischaracterizes the nature of the charge against her. While Count One includes the defendant's failure to inform the FDA about the slide sets she received from the doctors – or, in the alternative, notify FDA that she was no longer going to provide the slide sets – it extends further to a pattern of deception and concealment. The defendant is charged with corruptly obstructing, influencing, and impeding an official proceeding by (1) making false and misleading statements and (2) concealing information. The testimony and exhibits admitted during the government's case-in-chief have amply demonstrated both.

The United States has provided evidence establishing that the defendant was in charge of the effort to respond to the FDA's inquiry, had direct contact with Dr. Pradko and discussed the problematic nature of his presentations, was aware that Dr. Hudziak engaged in off-label promotion of Wellbutrin, sent admonishing letters to 28 other doctors, and thus knew the truth about GSK's off-label promotion. Her denials of off-label promotion and her statement that "all of the information consistently and clearly points to the conclusion" that GSK was not promoting Wellbutrin off-label were false and misleading. On top of this, the defendant assured the FDA that she would provide the agency with information responsive to its request. Then, while disclosing relatively minor problems at the company and giving the FDA a limited number of speaker promotional slides and (different, non-promotional) speaker training slides, the defendant said her response to the FDA's request was final and complete, even as she withheld

and concealed slide sets of at least 30 promotional speakers – including the top two – that showed the extent of off-label promotion occurring at GSK. While the defense suggests that the defendant harbored some intent to revisit the scope of the FDA's request, the evidence is uncontradicted that – at the time of her responses – all parties understood the agreed scope of what the defendant had committed to provide on behalf of GSK. Holding that corporations and their attorneys are free to mislead and deceive the governnment (and may promise but then not provide information when it turns out to be damaging), so long as the government's request does not come in the form of a subpoena, would set dangerous precedent that if followed could cripple the ability of a myriad of government regulators to carry out their missions.

That the FDA's request was voluntary in nature rather than in the form of a subpoena is a red herring. Having undertaken to respond and affirmatively representing that she would provide the FDA with specific information, the defendant had a duty to respond truthfully, avoid false statements or misleading half-truths or disclosures, and inform the FDA if she determined that she no longer wished to provide previously promised information. As the Fourth Circuit has explained, there is a duty not to mislead by concealment even when there is no duty to speak. The Court explained:

> [A]lthough the existence of an independent disclosure duty "is relevant and an ingredient" in some fraud prosecutions, such a duty is "not an essential in all such cases." . . . However, "active or elaborate steps to conceal" information can constitute such a scheme. Concealment often is accompanied by an affirmative misrepresentation or a violation of an independent statutory or fiduciary disclosure duty, but neither is "essential" for actionable fraud. What is essential is proof of a "scheme or artifice to defraud," which can be shown by deceptive acts or contrivances intended to hide information, mislead, avoid suspicion, or avert further inquiry into a material matter.

United States v. Colton, 231 F.3d 890, 900 (4th Cir. 2000) (citations omitted).

See also Commonwealth Land Title Ins. v. IDC Properties, 547 F.3d 15, 22 (1st Cir. 2008) ("[I]t is clear that a half-truth or failure to speak when necessary to qualify misleading prior statements does amount to a misrepresentation."); *United States v. Blastos*, 258 F.3d 25, 28 (1st Cir. 2001) (upholding mail fraud jury instruction providing that the "term false or fraudulent pretenses . . include actual, direct false statements as well as half-truths and the knowing concealment of facts"); *Romero-Barcelo v. Acevedo-Vila*, 275 F. Supp.2d 177, 191 (D.P.R. 2003) (noting, in the context of an attorney ethics issue, "courts have held that the rule against dishonesty can be violated by silence or a failure to speak, including conduct that involved no express misrepresentations but simply consisted of a failure to reveal underlying facts which might be necessary to avoid misleading someone."); *Sanford v. National Ass'n for Self-Employed*, 2009 WL 1460768, *10 (D. Maine 2009) (unpublished) ("[O]ne who voluntarily elects to make a partial disclosure is deemed to have assumed the duty to tell the whole truth, i.e. to make full disclosure even though the speaker was under no duty to make the partial disclosure in the first place." [citations omitted]); *Massachusetts v. Mylan Laboratories*, 608 F. Supp.2d 127, 156 (D. Mass. 2008) ("Although there may be 'no duty imposed upon one party to a transaction to speak for the information of the other . . .if he does speak with reference to a given point of information, voluntarily or at the other's request, he is bound to speak honestly and to divulge all material facts bearing upon the point that lie within his knowledge. Fragmentary information may be as misleading . . . as active misrepresentation, and half-truths may be actionable as whole lies.")

2. The Evidence Demonstrates the Defendant's Corrupt Intent

A reasonable jury could conclude that the defendant took deliberate action to conceal the relevant facts from the FDA, while creating the appearance of cooperation and candor. The notes of meetings at which the defendant was present document repeated discussions of taking information considered negative for GSK out of the production, including specifically the physician slide sets and the gifts, entertainment, and other compensation provided to attendees. They also demonstrate that Stevens requested and chose a more aggressive tone and presentation in the conclusion of what she originally intended to be her final letter to the FDA, despite advice from outside counsel that it might be too much so.

There is ample evidence for a reasonable jury to conclude that this was not mere negligence. It was a deliberate attempt to conceal "incriminating" evidence and avoid regulatory action. Stevens deliberately sought to mislead the agency as to the scope of the problem and conceal the evidence that demonstrated that scope. *See Harvey*, 532 F.3d 326, 334 (holding that a reasonable jury may infer intent to defraud from a pattern of fraudulent conduct). A reasonable jury could read the defendant's own statement that she intended to "let them [FDA] come back despite 10/29/02 statement" [GX 10 at 158] indicates she was aware she was obligated to produce the slide sets and other information to the FDA, but that she was choosing to violate that obligation. A reasonable jury could also legitimately read this note to indicate the defendant's attempts to set up a further meeting with the FDA do not negate the defendant's corrupt intent, especially in light of her intent (as also reflected in the notes) to lie about GSK's ability to provide the slides if FDA asked for them yet again.

C. The United States Has Provided Substantial Evidence of the Defendant's

Guilt With Respect to Count Two

As with Count One, the defendant mischaracterizes the nature of Count Two. The Indictment charges the defendant with a wide range of conduct involving the concealment and falsification of records, documents, and tangible objects. The United States has provided evidence that the defendant falsified the promotional speaker spreadsheets provided to the FDA by deleting a column related to speaker compensation – but it has also provided substantial evidence that the defendant concealed speaker slide sets showing off-label. As discussed above, having undertaken to respond and affirmatively representing that she would provide the FDA with specific documents and information, the defendant had a duty to respond truthfully, avoid misleading half-truths or disclosures, and inform the FDA if she determined that she no longer wished to provide previously promised information. Further, the evidence has demonstrated that the defendant falsified the documents (her letters) provided to the FDA in an effort to impede, obstruct, and influence the government's investigation. Her failure to provide responsive, promised, "incriminating" evidence, coupled with the false assurances in her letters that GSK was not promoting Wellbutrin off-label and that her response was final and complete, demonstrate that she knowingly altered, concealed, covered up, and falsified documents. The defendant's own notes – which have been admitted in their entirety and of which only a few selected excerpts have been read to the jury – along with her actions provide evidence of her wrongful intent.

The defendant's contention that she relied in good faith on the other lawyers on her team is a matter of fact to be decided by the jury. The evidence has shown that while a great deal of information was provided to the lawyers from King & Spalding, the King & Spalding lawyers

did not receive all of the information that the defendant had and did not know as much about the extent of the off-label promotion as the defendant. Also, there has been no evidence that any lawyer advised the defendant to make false statements and withhold information. Even if there had been such legal advice, it would have been unreasonable for the defendant – herself an experienced pharmaceutical company lawyer – to have done so.

D. The United States Has Provided Substantial Evidence Demonstrating that the Defendant Does Not Qualify for the Safe Harbor Under 18 U.S.C. § 1515(c)

The defendant's contention that the safe harbor provision of 18 U.S.C. § 1515(c) applies only when a lawyer's entire course of representation "was a sham, undertaken for criminal rather than genuine purposes" is without merit. As the Court recognized in its proposed jury instruction, a lawyer cannot qualify for safe harbor if she "counsel[s] or assist[s] a client in the commission of a crime." Court's Proposed Jury Instructions at 55.

E. The United States Has Provided Substantial Evidence of the Defendant's Guilt With Respect to Counts Three through Six

The United States has provided substantial evidence that each of the statements charged in Counts Three through Six can support a violation of 18 U.S.C. § 1001, and the defendant's description of the government's case distorts the evidence presented. For example, the defendant contends that no reasonable jury could determine that the defendant made a materially false statement with respect to advisory boards. The defense conceded during its opening statement that the defendant's statement about advisory boards was inaccurate. During the first day of testimony, FDA employee Sonny Saini testified that information about the frequency and type of advisory boards was capable of influencing the FDA's investigation – thus satisfying the

materiality element:

Q. If GSK had been holding significantly more than two local advisory boards per year per region, is that information that you believe the FDA would have been interested in?

A. Yes, we would have been interested in that information.

Q. Why?

A. Because if they're giving too many advisory boards, they might be influencing doctors and telling them potentially off-label uses or other inappropriate messages to go out to the local community and educate other health care providers on this inappropriate information.

Q. Would information that GSK paid for numerous special issue boards in certain regions in 2001-2002 have been capable of influencing the FDA's decisions in this matter?

A. Sorry. Could you repeat the question?

Q. Would information that GSK had paid for numerous local advisory boards or special issue boards in certain regions in 2001-2002, would such information have been capable of influencing the FDA's decision making?

A. Yes.

Q. Could you explain that?

A. Similar reason. We want to find out what type of consulting fees are out there and how many of these advisory boards are actually ongoing because, again, they could be incentivized to provide inappropriate information to the health care providers in a local area.

Tr. at 57:13 - 58:16 (Testimony of S. Saini, Apr. 27, 2011).

Despite the defendant's suggestion, her statements regarding GSK practices expressly went beyond whether GSK had some sort of official corporate policy of promoting off-label. For example, on February 28, 2003, the defendant stated, "GSK has not developed, devised, established, or maintained *any* program *or activity* to promote or encourage, *either directly or indirectly*, the use of Wellbutrin SR as a means to achieve weight loss or treat obesity" (emphasis added). On May 21, 2003, the defendant continued to represent that GSK did not engage in off-label marketing activities: "In the final analysis, all of the information consistently and clearly points to the same conclusion - GSK has not developed, devised, established, or maintained *any* program or activity to promote, either directly or indirectly, the use of Wellbutrin SR to achieve weight loss or treat obesity" (emphasis added). On November 6, 2003, the defendant again proclaimed that "GSK has not developed, maintained, or encouraged" the promotion of Wellbutrin for any unapproved indication.

Thus, the defendant did not simply represent to the FDA that GSK did not have a "corporate plan" to promote Wellbutrin off-label; rather, her letters said GSK was not promoting Wellbutrin off-label, period. The FDA's request for information was not limited to the official business plans put together by Jamie Millar and the five to six other employees in the Wellbutrin marketing department at GSK's home office in North Carolina. To the contrary, the evidence has shown that the FDA wanted to know how the company was actually promoting Wellbutrin in the field, where 70% of its employees worked and where all of the speaker programs took place. Cynthia Kelley testified that in 2001-2002 the company employed thousands of sales representatives, whose compensation was determined in part by how many prescriptions for GSK drugs their doctors wrote. There is no dispute that GSK was responsible for what was said

by Drs. Pradko, Hudziak, Wolkowitz, and the other 28 doctors who were identified as having off-label material -- and the evidence is clear that the defendant knew these doctors were promoting Wellbutrin off-label. As the defendant recognized, paying doctors large amounts of money to speak (off-label) at hundreds of promotional programs per year could be viewed as off-label conduct by the FDA. As she wrote in her notes:

PRADKO ISSUE

—> det'd that he has been discussing WBSR at GSK-sponsored events & using off-label info –

Broader issue: what has Co done? What is risk to Co. w/ respect to the rel. w/ [DR. P]
– Is he someone we have invested a great deal of $ in, liking what he says; providing him opps for $

Govt might say:
FDA: off-label – Co. liked it/condoned it as evid'd by proliferation of prez
OIG: paymts to [DR. P] at issue —> pay to Rx?

[GX 10 at 79]. In short, GSK's Wellbutrin speaker program was a de facto corporate program to promote the drug for uses the FDA had not approved as safe and effective.

But even if the Court were to accept the defendant's characterization of the evidence and the law,[1] the defendant would not be entitled to acquittal as to Counts Three through Six. These

[1] If it would be helpful to the Court, the United States can provide additional briefing with respect to each of the defendant's false statement arguments. The United States has not had

Counts charge the defendant both with making false statements and by using each of her letters to falsify, conceal, or cover up a fact by trick, scheme, or device. Section 1001 may be violated in either of these ways. The defendant's proposed jury instructions on Count Three make clear that she shares this understanding of the law. In each of her letters, the defendant concealed from the FDA information that she knew and evidence she had obtained, despite making commitments to provide that information and evidence, and falsely representing that her response was final and complete. Even if the jury determines that no false statements occurred, it could still reasonably convict on Counts Three through Six by determining that the defendant concealed or covered up a fact by trick, scheme, or device.

time to review thoroughly seven days of trial transcripts to respond fully to the defendant's motion filed on Sunday afternoon.

III. Conclusion

For the foregoing reason's, the defendant's motion should be denied.

Dated: May 9, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2011, a copy of the foregoing UNITED STATES' OPPOSITION TO DEFENDANT'S MOTION FOR JUDGMENT OF ACQUITTAL was electronically filed with the Court and served on defense counsel listed below via ECF:

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